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David A. Neumann, Ph.D.
Health Policy Analyst
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

Re: Comments on Draft Regulations: Waiver Applications for Participation in the Atlantic Cardiovascular Patient Outcomes Research Team Study of Nonprimary Percutaneous Coronary Interventions Performed in Maryland Hospitals Without On-Site Cardiac Surgery (COMAR 10.24.05)

Dear Dr. Neumann:

Adventist HealthCare appreciates the opportunity to respond to the Commission's request for comments on the above-referenced draft regulations. Adventist HealthCare is highly experienced in providing a high volume of Percutaneous Coronary Interventions ("PCIs") annually, both in hospitals with and without on-site cardiac surgery. Shady Grove Adventist Hospital has participated in the C-PORT study since its Maryland inception. Since then, it has established itself as a high volume provider of primary PCI services, with quality outcomes. Our comments are offered from our perspective as a hospital system that is familiar with the infrastructure necessary to build an effective primary and nonprimary PCI program, that will achieve excellent outcomes, enhance access to care and retain the support of experienced interventional cardiologists.

Adventist HealthCare wishes to express its support for the program envisioned by draft regulations. We also have some additional comments intended to enhance this initiative, including suggestions for review criteria that are focused on the goals of this study and will support its successful result. We are concerned that, without certain revisions, the approval criteria for selection of waiver hospitals may risk the C-PORT study yielding insufficient data to accomplish the intended result.

Important data will be gathered through this new C-PORT program, from cases reflecting the safe and effective performance of nonprimary PCI in the waiver hospitals. This first cohort of six hospitals should, we submit, be able to provide guidance from which other hospitals can

benefit as access to PCI is enhanced going forward. It is important that, for sufficient volumes and data to be gathered, the six selected programs should be located at hospitals that have a demonstrated ability to attract and sustain support from the interventional cardiology community and their patients. A proven track record, demonstrated by volumes, performance and outcomes, should be principal factors because they demonstrate what hospitals seeking this waiver have accomplished, versus what they propose to do. For useful data to be gained through programs that are both safe and effective, the Commission's draft regulations, especially the review criteria, could go further to ensure that nonprimary PCIs are performed at hospitals with the best performance and the most experienced interventional cardiologists, supported by well equipped and experienced clinical staff. We would propose the following additions to the draft regulations:

One Time Process

Under .02A, the Chapter refers to a "one-time" process for obtaining the waiver. Section .05B refers to the Commission's process for renewing waivers. You may wish to consider making the reference to a "one-time, renewable" waiver.

Allocation of Six Hospitals

Section .02C confirms that there will be a total of six hospitals granted a waiver. While some of the criteria are common to all hospitals, others vary depending on the region in which the waiver program will be located. Those outside the Washington Metropolitan and Baltimore Regions may have been in operation for a shorter period, or have lower volumes. Currently, the draft regulations note that the Commission "may consider" an applicant's current performance under its primary PCI waiver; we recommend that this be the primary consideration the Commission will consider.

We recommend that the allocation of waived programs among the six hospitals should ensure that several of those approved will be among those with a proven track record showing higher volumes of primary PCI over a longer period, with high quality outcomes. The evaluation should give greater weight to what hospitals have done, than what they promise to do. This will not only ensure that nonprimary PCI patients will be served in hospitals that have a demonstrated history of safety and effectiveness, but it will better ensure that there will be sufficient cases to sustain the efficacy of the C-PORT study.

Adventist suggests that facilities applying for a waiver should demonstrate a track record of performance in critical, measurable areas. These areas would include:

a. A mean "door to balloon" time of 120 minutes or less for at least 80% of all patients,

b. An annual volume of at least 50 Primary PCI cases per year,

c. Staff participation in at least 75 Primary PCI cases per year,

d. A complication rate of less than 4%,

e. A mean time delay of no more than 90-120 minutes between the onset of any complications encountered during the PCI and the onset of treatment from a qualified and credentialed cardiac surgery team, and

f. Patient outcomes that meet or exceed the national average from ACC-NCDR data.

Staffing

We recommend additional detail about the adequacy of staff should be provided under Section .04A(2)(b). The establishment of a safe and effective nonprimary PCI program, with necessary volumes to support the C-PORT study, is also dependent on the effectiveness of the entire hospital team. Section .04A(2)(b) does not distinguish between applicants who have an established team of 3 or more interventional cardiologists and those who propose to recruit them. It is logical and appropriate, when considering a new waiver program such as this, to give greater weight to hospitals with existing teams that include trained staff and three or more interventional cardiologists, than those promising to recruit such teams and cardiologists. This is more than a safety issue. The success of the study is dependent on it yielding sufficient data. The willingness of interventional cardiologists to use the nonprimary PCI programs can be affected by the characteristics of the staff. We recommend a preference for hospitals with a trained, experienced staff sufficient to handle the total volumes of primary and nonprimary PCI.[1]

Approval Factors

In addition to the above comments that we recommend be included in the approval factors, following are some brief, additional comments on the qualifications set out in the draft regulations.

[1] As a technical point, we assume that Section .04A(2)(b)(ii) is intended to state that one of the interventional cardiologists will be available within 30 minutes when on call.

Section .04A(3)(a) refers to an applicant's potential to improved geographic distribution of cardiovascular services. Does this refer to services other than access to PCI? Is participation in the C-PORT study linked to non-PCI related cardiovascular services?

We urge consideration of the fact that access to care is not simply a matter of "geographic distribution," which should be a secondary factor for the purposes of this study. For example, hospitals that are located in dense population areas provide essential access not reflected in geographic distribution. Access to a program with a demonstrated track record, an established team, and historically high volumes with quality outcomes should be the primary basis for site selection among this initial group of study hospitals. After a successful nonprimary PCI C-PORT study, other hospitals will be able to build on the knowledge and experience of this first group, further enhancing access. This is what happened as additional hospitals are now offering primary PCI, building on what has been learned from the initial group of C-PORT hospitals offering primary PCI.

Maintaining a Waiver

The draft regulations identify the conditions under which a waiver to perform nonprimary PCI should be maintained and may be subject to being relinquished. The draft regulations describe waiver surrender as "immediate" under certain circumstances. When a significant clinical program has to be ended, there has to be an appropriate process in place to ensure a smooth transition. To ensure there is no confusion about when a program may not be maintained for any of these cited reasons, we suggest that this refer to "immediately on notice" from the Commission. In this way, the Commission can evaluate a particular situation, determine when and how the program needs to be ended and determine the final date when this should occur without undue disruption to patients and their physicians who would need to make alternate arrangements for services.

We appreciate the Commission moving forward with regulations supporting this important research project, the results of which will be an effective source of information in formulating future public policy on cardiovascular services. Thank you for the opportunity to comment on these draft regulations.

Sincerely,

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